



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,557	07/18/2002	Xucbao Li	2577-139	3290

6449 7590 12/17/2004

ROTHWELL, FIGG, ERNST & MANBECK, P.C.  
1425 K STREET, N.W.  
SUITE 800  
WASHINGTON, DC 20005

EXAMINER

BAUM, STUART F

ART UNIT	PAPER NUMBER
----------	--------------

1638

DATE MAILED: 12/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/089,557

Applicant(s)

LI ET AL.

Examiner

Stuart F. Baum

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2 is/are allowed.
- 6) ☒ Claim(s) 1 and 3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 April 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2/9/04, 4/1/02.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☒ Other: seq. search result.

### **DETAILED ACTION**

1. Claims 1-3 are pending and are examined in the present office action. Nucleotides 1 through 816 of SEQ ID NO:2 are included in the examination.

### ***Specification***

2. The specification is objected to because SEQ ID NO:2 of the sequence listing is disclosed as being a DNA molecule from Arabidopsis, but the specification discloses that SEQ ID NO:2 is isolated from cotton (page 4, lines 12-13).

### ***Written Description***

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1 and 3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a promoter that is cotton fiber-specific comprising the promoter of the cotton actin gene CFACT1 or a promoter that is cotton fiber-specific comprising an active fragment of nucleotides 1 through 816 of SEQ ID NO:2.

Art Unit: 1638

Applicants isolated a cDNA clone from a cDNA library made from young cotton fibers which was subsequently sequenced and identified as a CFACT1 cDNA fragment (pages 9 and 10). This fragment was used to isolate the genomic sequence which is listed as SEQ ID NO:2 (pages 13-14). Applicants disclose that the first 0.8 kb of SEQ ID NO:2 comprise the promoter.

The Applicants do not identify essential regions of the CFACT1 promoter sequence comprising bases 1 to 816 of SEQ ID NO:2, nor do Applicants describe any fragments of said sequences that has the activity of bases 1 to 816 of SEQ ID NO:2. The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of CFACT1 promoter sequences that direct expression in the same spatial and temporal pattern as nucleotides 1 to 816 of SEQ ID NO:2 or Applicants fail to describe promoter fragments of bases 1 to 816 of SEQ ID NO:2 that direct expression in the same spatial and temporal pattern as bases 1 to 816 of SEQ ID NO:2.

Art Unit: 1638

Applicants only describe a single promoter sequence comprising bases 1 to 816 of SEQ ID NO:2. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for the promoter sequence of bases 1 to 816 of SEQ ID NO:2, it remains unclear what features identify a cotton fiber-specific promoter of bases 1 to 816 of SEQ ID NO:2. Since the genus of CFACT1 promoter sequences comprising bases 1 to 816 of SEQ ID NO:2 has not been described by specific structural features, the specification fails to provide an adequate written description to support the breadth of the claims.

#### ***Scope of Enablement***

4. Claims 1 and 3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a cotton fiber-specific promoter comprising bases 1 to 816 of SEQ ID NO:2, does not reasonably provide enablement for any cotton fiber-specific promoter comprising any promoter of any cotton fiber-specific actin gene CFACT1 or any promoter comprising any fragment of bases 1 to 816 of SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of

Art Unit: 1638

experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to a promoter that is cotton fiber-specific comprising the promoter of the cotton actin gene CFACT1 or a promoter that is cotton fiber-specific comprising an active fragment of nucleotides 1 through 816 of SEQ ID NO:2.

Applicants isolated a cDNA clone from a cDNA library made from young cotton fibers which was subsequently sequenced and identified as a CFACT1 cDNA fragment (pages 9 and 10). This fragment was used to isolate the genomic sequence which is listed as SEQ ID NO:2 (pages 13-14). Applicants disclose that the first 0.8 kb of SEQ ID NO:2 comprise the promoter, which was subsequently operably linked to the GUS reporter gene and transformed into cotton and tobacco (pages 14-19, Example 3). Transgenic cotton exhibited GUS activity only in young fibers and transgenic tobacco exhibited GUS activity in seeds (paragraph bridging pages 18 and 19).

The state-of-the-art teaches using pieces of a promoter that do not contain the full complement of cis-acting elements, will not produce the expression profile as observed using the whole promoter fragment. Kagaya et al (1995, Mol. Gen. Genet. 248 :668-674) teach the rice chloroplastic aldolase promoter contains two elements, one of which acts as a negative element while the other acts as a positive element that confers developmentally regulated mesophyll cell specific expression. Removal of either of these regions changes the normal expression pattern

Art Unit: 1638

(page 670, left column). Kagaya et al also teach that the promoter contains an element that serves as a target for light induction (abstract).

Benfey et al (1990, Science 250:959-966) teach that the 35S CaMV promoter consists of domains that individually regulate spatial expression within plants. "The combination of each of the five B subdomains with domain A results in an expression pattern that differs from that of the individual subdomains or domain A" (page 961, left column, 2<sup>nd</sup> paragraph). In other words, deleting a required domain will jeopardize the proper spatial and temporal expression pattern. In addition, Benfey et al (1989, EMBO J, 8(8):2195-2202; page 2200, left column 2<sup>nd</sup> paragraph) teach that not only are the promoter domains important for specifying proper spatial and temporal expression but that when all domains were present, the quantity of expression increased.

Applicants have not disclosed how one makes or isolates any of the sequences that are encompassed by Applicants' broad claims. Applicants have not taught which regions of the respective polynucleotides can be used to amplify any of said polynucleotides or which regions can be used as a probe to isolate any of said polynucleotide sequences.

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified sequences, either by using non-disclosed fragments of bases 1 to 816 of SEQ ID NO:2 as probes or by designing primers to undisclosed regions of bases 1 to 816 of SEQ ID NO:2 and isolating or amplifying fragments, subcloning the fragments, producing expression vectors and transforming plants therewith, in order to identify those, if any, that when over-expressed direct expression in cotton fibers.

Art Unit: 1638

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

***Claim Rejections - 35 USC § 102***

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claim 3 is rejected under 35 U.S.C. 102(a) as being anticipated by Miki et al (October 1999, WO 99/53067-A2).

The claim is drawn to a promoter that is cotton fiber-specific comprising an active fragment of the promoter sequence of nucleotides 1 through 816 of SEQ ID NO:2.

Miki et al disclose SEQ ID NO:9 which comprises a promoter set forth in bases 1-5514 of SEQ ID NO:9, and said region exhibits 49% identity with Applicants' nucleotides 1-816 of SEQ ID NO:2. The sequence of Miki et al directs expression in the seed coat of soybean and also in trichomes. It would be inherent that the promoter sequence of Miki et al would express in cotton fibers given that both cotton fibers and trichomes comprise cells of the epidermis of seeds and given that Applicants' sequence also directs expression in the seed coat of non-cotton plants, e.g., of tobacco (paragraph bridging pages 18 and 19). Given Applicants' definition of fragment, "A fragment can comprise excisions, deletions, truncations or substitutions of the sequence of nucleotides 1-816 of SEQ ID NO: 2, or a combination of these" (page 7, lines 19-22), and as such, Miki et al anticipate the claimed invention.

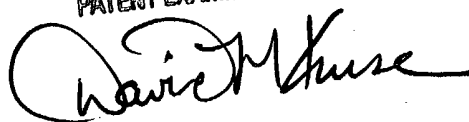
Art Unit: 1638

6. Claim 2 is deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated polynucleotide of bases 1 to 816 of SEQ ID NO:2.
7. Claim 2 is allowed.
8. Claims 1 and 3 are not allowed.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Stuart F. Baum Ph.D.  
Patent Examiner  
Art Unit 1638  
December 8, 2004

DAVID H. KRUSE, PH.D.  
PATENT EXAMINER  


10261 for clm3

RESULT 6  
ID AA229911/c  
XX AA229911 standard; DNA; 8310 BP.  
AC  
XX AA229911;  
XX  
XX 26-JAN-2000 (first entry)  
XX  
XX CDNA encoding a SC4 protein of soybean.  
XX  
XX Promoter; seed coat specificity; SC4 protein; herbicide resistance gene;  
XX  
XX Viral coat protein; biological control; Bt toxin; seed taste; ss.

OS Glycine max.  
XX  
XX Key Location/Qualifiers  
FH 1..5514  
FT Promoter /\*tag= a  
FT /note= "claimed"  
XX  
XX WO953067-A2.  
XX  
XX 21-OCT-1999.  
XX  
XX 13-APR-1999; 99WO-CA000293.  
XX  
XX 13-APR-1998; 98US-00059090.  
XX  
XX (MNC) CANADA MIN AGRIC & AGRI-FOOD CANADA.  
XX  
XX PA  
XX PI Mikl B, Gjzen M, Miller S, Bowman L, Batchelor A, Hu M;  
XX PI Boutiller K;  
XX WPI; 1999-611304/52.  
XX  
XX PT Novel promoter sequences and genes useful for inducing expression of  
XX PT genes in plant seed coats.  
XX  
XX PS Claim 36; Page 147-155; 155pp; English.  
XX  
XX CC The present sequence encodes a SC4 protein. The promoter of this gene is  
XX CC differentially expressed in seed coat tissues, specifically within the  
XX CC outer integument, the inner integument, the thick walled parenchyma, the  
XX CC thin walled parenchyma, the endocarp, the endocarp cells, the  
XX CC palisade, the stele parenchyma, or the membranous endocarp associated  
XX CC with the seed coat. The seed-coat promoters may be used to express  
XX CC proteins of interest in seed coat tissues. Genes of interest include but  
XX CC are not restricted to herbicide resistance genes, genes encoding viral  
XX CC coat proteins, or genes encoding proteins conferring biological control  
XX CC of pests or pathogens, e.g. a Bt toxin. Other genes that may be expressed  
XX CC include proteins that alter the taste of the seed and/or affect the  
XX CC nutritive value of the seed  
XX  
SQ Sequence 8310 BP; 2807 A; 1283 C; 1265 G; 2955 T; 0 U; 0 Other;  
Query Match 11.9%; Score 97; DB 2; Length 8310;  
Best Local Similarity 48.9%; Pred. No. 0.0008;  
Matches 291; Conservative 0; Mismatches 300; Indels 4; Gaps 1;  
QY 160 TAGTGAAGTATTTTCATGAGGTGTAAGATTAATGTTATGGATACATATTC 219  
Db 4944 TTTTAAATTTAAATAATTTTATGAAATTAATAAATTAATAAATCCTTTATA 4885  
QY 220 TAGTATTAATGCTGTTGAAGTAAATTAATTAATTAATCAATCCTGTTTATTTT 279  
Db 4884 AATCCTTTAAATTTCTGTATGATTAATTAATTAATTAATTAATTAATTAATTA 4825  
QY 280 TTTTATTAACAACATTAACAATTAATTTTAACTTGTGTTTCAATTAACCGT 339  
Db 4824 TATATATTAATTAATTAATTAATTAATTAATTAATTAATTAATTAATTAAT 4765  
QY 340 TAAATTTTAAATTAATTAATTAATTAATTAATTAATTAATTAATTAATTAAT 399  
Db 4764 TAAATTAATTAATTTTAAATTAATTAATTAATTAATTAATTAATTAATTAAT 4705  
QY 400 TATGTAATAATTAATTAATTAATTAATTAATTAATTAATTAATTAATTAAT 459  
Db 4704 TGT---AAATACCTTAATTAATTAATTAATTAATTAATTAATTAATTAAT 4649  
QY 460 TAAAGAATTAATTAATTAATTAATTAATTAATTAATTAATTAATTAATTAAT 519  
Db 4648 TTTAGAAAAAATCTGTTAATTTTATTTTAACTTAATTAATTAATTAATTAAT 4589  
QY 520 TAAACAAATAGAAATTTTTCAGGTTCAACCAACCAAGAAATTAATTAATTAAT 579  
Db 4588 TTTTCAATATCAATTAATTAATTAATTAATTAATTAATTAATTAATTAATTAAT 4529

Tue Sep 21 10:21:02 2004

us-10-089-557-2\_copy\_1\_816.rng

Page 6

QY 580 CAGAAAGTAAATCATTTCAGAAATATTTTCGAAATTATTTTACTGGCAACAA 639  
DB 4528 TATATTAATTTATTTATGTAATGATAAATTAATCTACATTTATTTATATATTA 4469  
QY 640 TCGAGTCTAGTGTCTGTTTATTTTATTTTCTATTTAGAGAACTAGAAATTG 699  
DB 4468 TGAATAAGTTTATTTATTAATTAACAGTAATTAATTTAAATTAGATTAGTTAAATG 4409  
QY 700 ATTGTCAATGCTTTTAACTAGCTGTGTTAGATTAGTTGAAGGCAAGAAC 754  
DB 4408 TTATTTTAAATCTACTTAATTTTCAATTAATTAATTAATTAATTAATTAATC 4354